Date of report: 6/15/07

Principal Investigator(s): Leslie Wilson, Ph.D. and Janine Ramsey, Ph.D.

Title of project: Collaboration on Identification of risk and Cost-effectiveness of Chagas Disease in the Mexican and California Blood Supply by Geographic Migration

Narrative Report

This project was very extensive as we screened 2,029 blood donors and surveyed 613 at 5 California Blood banks. This project also received some visibility with the blood banks because Ortho Diagnostics was in the process of developing a serology test for Chagas for the US blood supply and this was just approved in Dec. 2006. This led to the blood centers in the United States needing to determine the best methods for implementing the new serology testing and our study addresses the cost-effectiveness of different approaches to serology testing which the blood banks find very useful in their decision making. Our estimates were only possible through estimation of risk using migration and immigration history mapped to serology risk from Mexican blood banks. Therefore there has been close collaboration with both the California and Mexican the blood banks and we hope more collaboration in the future as we map our survey results using Mexican blood risk to the actual serology results that are now being conducted in the United States. In addition, we would like to determine what the health effects are on those immigrants residing in California who are testing Chagas positive when donating blood.

In addition, we are still collecting data in Mexico on the relationship of serology risk with migration patterns. Attached below are the two abstracts which briefly explain our results.

Abstract #1: Cost-effectiveness of Chagas Screening Strategies

Introduction:
Although the U.S. is not endemic for T. cruzi, up to 100,000 immigrants may have asymptomatic Chagas. The first enzyme-linked immunosorbent assay (ELISA) test for detection of T. cruzi antibodies was approved by F.D.A. Dec. 2006 and blood banks are beginning to serology test for Chagas. However there is no recommendation on the best method of implementing serology testing.

Purpose:
Estimate Chagas risk by travel and residence history of California blood donors through donor surveys and develop a Markov model to determine cost effectiveness of 3 approaches for implementing Chagas testing in US blood banks.
Methods:
We screened 2,029 donors at 5 CA sites for 3 risk based questions: If they or their birth mother were born or ever lived or traveled in Latin America (LA) for >2 weeks. The 481 responding yes answered a survey asking about LA residence and travel history by city, Chagas risk factors, and knowledge. Donor risk was assigned based on known risk at the highest and lowest residence or travel risk. The Markov model compared three scenarios: Serology testing all donations, Serology testing only positives of verbal screening questions, and no serology testing. The model included risk by living/travel history, urban/rural status, blood type, sensitivity and specificity of verbal screening and ELISA testing, and probability of infection. We modeled all Chagas disease states, started at transfusion age 60, and included a 15 year delay in chronic phase symptoms and an increased transfusion death rate. Chagas treatment cost $64,631, ELISA testing $7.50/unit, and verbal screening $3.15/donor.

Results:
Testing all blood donations with an ELISA for T. cruzi is cost effective compared with no testing, being both less costly and saving 0.00135 more life years. It is not cost-effective (CE) to serology test all compared to verbally screening and serology testing positives only; costing $6 million added dollars for each added life year saved. When adjusting our risk numbers to the tested Chagas risk, the CE rises to $74 million per life year saved, indicating we can save $74 million for each additional life year lost if we verbally screen. Life years lost when not serology testing all is 1 in 10,000 blood units. The model is most sensitive to risk estimates, transfusion mortality, and testing costs.

Conclusions:
The new FDA licensing to test for Chagas disease in US blood banks is cost-effective compared to the present practice of no testing even if implementing a procedure to test all donated blood. However, it is not cost-effective to serology test all donations compared to testing only those that screen positive verbally. Addition of verbal screening prior to serological testing should be considered as the most cost-effective option for the US.

Abstract #2: Comparison of Blood donor Chagas Risk across 3 California Sites

Author Block:
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¹UCLA, San Francisco, CA, United States, ²National Institute for Public Health, Cuernavaca, Mexico, ³Blood Systems Research Institute, San Francisco, CA, United States, ⁴National Center for Blood Transfusion, Mexico City, Mexico

Introduction: The US is not endemic for T. cruzi, but up to 100,000 US immigrants may be unknowingly Chagas infected. Following the recent FDA approval of an ELISA test for detection of T. cruzi antibodies, blood banks must assess likely donor risk without clear data.
Purpose:
To compare donor Chagas risk by travel/residence history and characterize at risk donors across 3 distinct CA locations: San Diego (SD) a border area, Stockton/Modesto (SM) an agricultural area, and San Francisco (SF).

Methods:
We screened 2029 donors with a broad risk based question: If they or their birth mother was born or ever lived/traveled in Latin America for > 2 weeks. The 481 that screened positive took a survey about residence/travel history, Chagas knowledge and risk factors. Each donor was assigned a risk based on known risk of places lived/traveled. Pearson’s Chi-square 2-sided statistical test was used to compare data across sites.

Results:
We found significant differences in % screening positive for any risk (24%) (PChi=20.6, Pr<0.001) with more in SD (28%) and less in SM (15%) than expected. Calculated Chagas risk of all donors (0.004) was highest in SF (0.007) and lowest in SM (0.002).

We found a significant difference in live (PChi=15.9 Pr=0.014) and travel (PChi=29.0 Pr<.001) history across sites. In SD more donors and in SM fewer donors lived/traveled in Mexico than expected. More SF donors lived/traveled in Central/South America than expected.

There was no sig. difference in % of donors surveyed who consider themselves Hispanic despite sig. differences in risk history and census identified Hispanics across sites.

Conclusion:
Verbal screening may lessen the US testing burden by as much as 68%. The calculated risk of CA blood donors varies across sites but is higher than the recently reported 0.0003 serology risk. We caution against strategies testing only in areas with high % Hispanics because surveyed risks did not follow surveyed Hispanic self-identity.
Names of collaborating scholars and their institutions (if applicable):
Leslie Wilson, Ph.D. UCSF San Francisco, CA
Janine Ramsey Ph.D. Instituto Nacional de Salud Publica (National Institute of Public Health Cuernavaca, Mexico
Stefano Bertozzi, MD, Ph.D. Instituto Nacional de Salud Publica (National Institute of Public Health Cuernavaca, Mexico
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Brian Custer Ph.D., Blood Systems Research Center, Blood Centers of the Pacific San Francisco, CA
Kim Anh Nguyen MD, Blood Centers of the Pacific San Francisco, CA
David Oh, MD, San Diego Blood Banks
Nora Hirschler, MD, Blood Centers of the Pacific San Francisco, CA
Elyady H Podesta, Delta Blood Banks. Stockton CA
Celso Bianco America’s Blood Centers of the Pacific, Washington, DC.

Names, disciplines, and institutional affiliations of participating graduate students who worked on the project:
Yelena Belkin-Koplowicz: Graduate Student at UCSF
Christi Motter: Graduate Student at UCSF

Extramural funding received by principal investigator, collaborators, or participating graduate students (please specify who) as outcome of UC MEXUS grant:
None

Proposals prepared for extramural funds:

Title:
Variations in Migration history and Serology Risk for California and Mexico
Agency to receive submission and amount of award:
PIMSA: Migration and Health Research Program

Publications by principal investigator, collaborators, or graduate students (please specify who) resulting from UC MEXUS grant: (submitted)
None
Submitted publications:

Author: Wilson Leslie S. Koplowitz, Yelena, Ramsey Janine, Motter Christi, et al

Title: Cost-effectiveness of Implementation Methods for Chagas Serology testing in the United State Blood Banks

Submitted to: Blood

Conference presentations related to UC MEXUS project:

1. Presenter: Wilson Leslie S.
   with: Ramsey Janine, Koplowitz, Yelena, Motter Christi, et al

   Title of paper: Cost-Effectiveness of Chagas Screening Strategies


2. Presenter: Koplowitz, Yelena

   Title of paper: Estimation of Risk of Chagas disease in the California blood supply: Costs and Risks from Mexican migration locations.

   Name, date, and location of conference: Western Pharmacoeconomics Meeting, March, 2007. Salt Lake City, Utah.

3. Presenter: Leslie S. Wilson, Ph.D.


   Location, date, Place: Biotecnologia: July 15, 2006, Corfu, Greece.

4. Presenter: Leslie S. Wilson and Janine Ramsey

   Title of Paper: Collaboration on identification of risk and cost-effectiveness of Chagas Disease in the Mexican and California blood supply by geographic migration.

   Location, Date, Place: Guadalajara, Mexico October 9-10, 2006. Binational Public Policy Forum on Migration and Health: Program de Investigacion en Migracion Y Salud (PIMSA).
Financial Report – University of California, San Francisco

Salaries and Benefits: None

Supplies and Expenses (please elaborate):

Total $24,696.78 consulting services for Kalista Bley at $17.20/hour -
December 2005 – 96 hours at $1,651.20
January 2006 – 100 hours at $1,720.20
February 2006 – 100 hours at $1,720.20
March 2006 – 111 hours at $1,909.20
May 2006 – 116 hours at $1,995.20
June 2006 – 105 hours at $1,806.00
July 2006 – 100 hours at $1,720.00
August 2006 – 77.75 hours at $1,337.30
September 2006 – 100 hours at $1,720.00
October 2006 – 100 hours at $1,539.40
November 2006 – 104 hours at $1,788.80
December 2006 – 92 hours at $1,582.40
January 2007 – 100 hours at $1,720.00
February 2007 – 100 hours at $1,720.00
March 2007 – 44.60 hours at $766.88

Travel (include names, means of travel, locations and dates):

$69.98 mileage reimbursement for Kalista Bley –
Travel to SF Bay Area blood banks – June 4 – June 29, 2006

$229.24 mileage reimbursement for Kalista Bley –
Travel from Berkeley to San Diego to visit San Diego area blood banks –
July 5 – July 26, 2006

Any funds paid to another institution through a subcontract: None

Other (please specify): None

TOTAL: $24,996.00

Dr. Leslie Wilson, Ph.D.
Principle Investigator, University of California San Francisco

PLEASE NOTE: ALL FUNDS UNEXPENDED AT THE END OF THE GRANT PERIOD MUST BE RETURNED TO UC MEXUS.
Financial Report - Instituto Nacional de Salud Publica

Salaries and Benefits:

$15,004 salary and benefits for Leopoldo Valiente, MPhD, for his role in collecting project data during the award period of September 1, 2005 to March 31, 2007.

Supplies and Expenses (please elaborate):

None

Travel (include names, means of travel, locations and dates):

None

Any funds paid to another institution through a subcontract:

None

Other (please specify):

None

TOTAL: $15,004.00

Dr. Janine Ramsey Willoquet, Ph.D.
Principle Investigator, Instituto Nacional de Salud Publica

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